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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,890	08/28/2000	Oliver Brustle	V0S-012	7106

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WILMER CUTLER PICKERING HALE AND DORR LLP  
60 STATE STREET  
BOSTON, MA 02109

EXAMINER
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FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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02/12/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/581,890

Applicant(s)

BRUSTLE, OLIVER

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 106-136.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

*Anne-Marie Falk*

ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER

Anne-Marie Falk, Ph.D.  
Primary Examiner  
Art Unit: 1632

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**Continuation Sheet (PTOL-303)****Continuation of 3. NOTE:**

The proposed amendment would require a new ground of rejection under 35 U.S.C. 112, first paragraph, for the introduction of new matter to the claims. The proposed amendment adds the limitation “regional-identity unrestricted pluripotent” which would be rejected as new matter. At page 15 of the response, Applicants assert that there is no *ipsis verbis* requirement for written description and that the newly added claim limitation may be supported in the specification through express, implicit or inherent disclosure. Applicants assert that one of skill in the art would understand the “pluripotent” nature of embryonic stem cells. However, the claims are not directed to embryonic stem cells or even compositions comprising embryonic stem cells, but instead are directed to cell compositions comprising embryonic stem cell-derived neural precursors, and neuronal or glial cells derived from the embryonic stem cell-derived neural precursor cells. The specification does not teach that the neural precursor cells are unrestricted or pluripotent. Furthermore, the specification does not define “regional-identity” or provide implicit support for “regional-identity” and any physical or functional properties intended to be associated with said regional-identity. As a further issue, a new ground of rejection under 35 U.S.C. 112, second paragraph, would be required because the newly added limitations of “unrestricted” and “pluripotent” is inconsistent with the body of the claim which does not include the presence of a pluripotent cell type. Thus, if entered, the proposed amendment would require multiple new grounds of rejection.

**Continuation of 11.** The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

At pages 9-10 of the response, Applicants argue that the Office Action of 8/14/2006 was not properly made final and Applicants request withdrawal of the finality. Applicants allege that the claims under consideration in that Office Action were not directed to the same invention and were not rejected

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**Continuation Sheet (PTOL-303)**

on the grounds and art of record. At page 10, paragraph 2 of the response, Applicants allege that the claims under consideration were not identical to claims previously considered. However, claim identity is not a criteria for making a proper final rejection. All that is required is that the claims are directed to the same invention. In the instant case, the claims under consideration were directed to the same invention.

At page 10, paragraph 3 of the response, Applicants allege that the claims were not rejected on the same grounds of record because the Examiner had not previously considered, and deemed "not ... persuasive as it pertains to the rejection under 35 U.S.C. 102(e)", the Second Declaration of Dr. Bruestle. Contrary to Applicants' assertion, finding Applicants arguments unpersuasive and providing reasons why those argument were not persuasive does not constitute a new ground of rejection. The argument was not found persuasive in overcoming the rejection of record and the rejection of record was maintained. Applicants are reminded that the rejection under 35 U.S.C. 102(e) was set forth in the Office Action of 12/2/2005 and was maintained in the Office Action of 8/14/2006 for reasons of record. No new ground of rejection was made. Applicants are further reminded that consideration of the Second Declaration of Dr. Bruestle was found to be partially persuasive and resulted in the withdrawal of the enablement rejection under 35 U.S.C. 112, first paragraph, over the majority of the claims. See the Office Action of 8/14/2006 at page 2, which states

The rejection of the prior pending claims under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn in view of the cancellation of these claims. The rejection has not been applied to the newly added claims in view of the new claim language, and further in view of the Declaration of Dr. Bruestle, which argues that cell compositions consisting essentially of different proportions of embryonic stem cell-derived neural precursor cells, and neuronal or glial cells derived from the embryonic stem cell-derived neural precursor cells, could be obtained by one of skill in the art based on the disclosure in the specification.

Thus, while rejections were withdrawn, no new rejections were made.

At page 11 of the response, Applicants assert that an interview was held after Final rejection, but prior to the Final rejection being discussed here and that a proposed amendment was considered by the

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**Continuation Sheet (PTOL-303)**

Examiner in the interview, wherein the Examiner pointed out some claim language that appeared to be new matter. The purpose of the interview was to assist Applicant in avoiding obvious errors in their next amendment, as there is no advantage to introducing claim language that would be subject to a new matter rejection. The amendment presented at the interview was not filed and a new amendment was prepared and filed instead on 5/1/06. The amendment was directed to the same invention and the claims were rejected on the grounds and art of record. While rejections were withdrawn, no new rejections were made. Furthermore, while the arguments submitted with the response were fully considered, the arguments were not found to be persuasive in overcoming the rejections of record and the rejections of record were maintained. In such a situation, it is proper to make the rejections and the Office Action final. Thus, the rejections were properly made final.

At page 12 of the response, Applicants point to proposed new Claims 137, 138, and 139 and assert that glial cells derived from embryonic stem cell-derived glial precursors are useful in pharmaceutical compositions for therapeutic purposes and further assert that Keirstead et al. (2005) supports this conclusion. Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted prior to a final rejection or after final rejection and submitted with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection. See MPEP 716.01. The newly filed evidence has not been considered.

Where Applicants' arguments are directed to the proposed amended claims, the arguments are moot because the proposed amendment has not been entered for the reasons noted hereinabove.

Therefore, the rejections under 35 U.S.C. 112, first paragraph (enablement) and second paragraph and under 35 U.S.C. 102(e) are maintained for reasons of record.

**Notice of Non-Compliant  
Amendment (37 CFR 1.121)**

Application No.

09/581,890

Examiner

Anne-Marie Falk, Ph.D.

Applicant(s)

BRUSTLE, OLIVER

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1632

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The amendment document filed on 16 January 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other \_\_\_\_\_.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other \_\_\_\_\_.
- ☐ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other \_\_\_\_\_.
- ☒ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: See Continuation Sheet.
- ☐ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):  
\_\_\_\_\_

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

**TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:**

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action. If any of above boxes 1. to 4. are checked, the correction required is only the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121.

**Extensions of time** are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

**Failure to timely respond** to this notice will result in:

**Abandonment** of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

**Non-entry** of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

*Anne-Marie Falk*

Legal Instruments Examiner (LIE), if applicable

ANNE-MARIE FALK, PH.D.

Telephone No.



Continuation of 4(e) Other:

The claim amendments are not in compliance with 37CFR 1.121(c)(3). 37 CFR 1.121(c)(3) provides that new claims shall be presented in clean version, without any underlining. See Claim 139..